PUBLIC HEALTH COUNCIL

Meeting of the Public Health Council, Tuesday, January 23, 2001, at 10:00 A.M., Massachusetts Department of Public Health, Henry I. Bowditch Public Health Council Room, 2nd Floor, 250 Washington Street, Boston, MA. Present were: Dr. Howard K. Koh (Chairman), Dr. Clifford Askinazi, Mr. Manthala George, Jr., Ms. Shane Kearney Masaschi, Mr. Albert Sherman, Ms. Janet Slemenda, Ms. Phyllis Cudmore, and Dr. Thomas Sterne; Mr. Benjamin Rubin absent. Also in attendance was Ms. Donna Levin, General Counsel.

Chairman Koh announced that notices of the meeting had been field with the Secretary of the Commonwealth and the Executive Office of Administration and Finance, in accordance with the Massachusetts General Laws, Chapter 30A, Section 11A1/2.

The following members of the staff appeared before the Council to discuss and advise on matters pertaining to their particular interests: Dr. Bruce Cohen, Ph.D., and Mr. Zi Zhang, M.B., M.P.H., Division of Health Statistics, Research and Epidemiology, Bureau of Health Statistics; Ms. Sally Fogarty, Assistant Commissioner, Bureau of Family and Community Health; Ms. Nancy Ridley, Assistant Commissioner, and Ms. Marie Eileen O'Nieal, Health Policy Coordinator, Bureau of Health Quality Management; Mr. Howard Wensley, Director, Division of Community Sanitation; Mr. Paul Hunter, Director and Mr. Roy Petre, Assistant Director, Childhood Lead Poisoning Prevention Program; Ms. Louise Goyette, Director, Office of Emergency Medical Services; Ms. Joyce James, Director and Mr. Jere Page, Senior Analyst, Determination of Need Program; and Deputy General Counsels Edmund Sullivan, James Ballin, Tracy Miller and Carl Rosenfield, Office of the General Counsel.

PERSONNEL ACTIONS:

In a letter dated January 10, 2001, Katherine Domoto, M.D., Associate Executive Director for Medicine, Tewksbury Hospital, Tewksbury, recommended approval of the appointments and reappointments to the provisional consultant, provisional affiliate, consultant and allied medical staffs of Tewksbury Hospital. Supporting documentation of the appointees' qualifications accompanied the recommendation. After consideration of the appointees' qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Associate Executive Director for Medicine of Tewksbury Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the following appointments and reappointments to the provisional, consultant, and affiliate medical staffs of Tewksbury Hospital be approved for a period of two years beginning January 1, 2001 to January 1, 2003:

APPOINTMENTS:

NAME:	MASS. LIC. NO.:	STATUS/SPECIALTY:
Krissie Connor, DO	207984	Provisional Affiliate Internal Medicine
Daniel Hallisey, DPM	2135	Provisional Consultant/Podiatry

REAPPOINTMENTS:

NAME:	MASS. LIC.NO.:	STATUS/SPECIALTY:
Debra DeFlumeri, RNC, MS	160537	Allied/Nurse Practitioner
Victoria Knowlton, RNC, MS	131213	Allied/Nurse Practioner
Jean O'Farrell, MS, RNC	145299	Allied//Nurse Practioner
R. James Statton, RNC, NP	1117192	Allied /Nurse Practioner
Steven Nisenbaum, PhD, JD	3670	Allied/Psychologist
Ann Teele, PhD	1360	Allied/Psychology
Phillip Gendelman, MD	46245	Consultant/Ophthalmology
Thomas Martin, PhD	2122	Allied/Psychology

In a letter dated January 3, 2001, Blake Molleur, Executive Director, Western Massachusetts Hospital, recommended approval of the appointment and reappointments of an optometrist and physicians to the consulting, active, and affiliate medical staff of Western Massachusetts Hospital, Westfield. Supporting documentation of the appointees' qualifications accompanied the recommendation. After consideration of the appointees' qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Executive Director of Western Massachusetts Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the following appointment and reappointments to the consulting, active, and affiliate medical staff of Western Massachusetts Hospital be approved:

APPOINTMENT:	STATUS/SPECIALTY:	LICENSE NO.:
Edward Walsh, O.D.	Consulting/Optometry	1828

REAPPOINTMENTS:	STATUS/SPECIALTY:	LICENSE NO.:
Rodney Larsen, M.D.	Active/Internal Medicine Geriatrics	38727
Jonathan Slater, M.D.	Affiliate/Internal Medicine Nephrology	81014

STAFF PRESENTATIONS:

"MASSACHUSETTS BIRTHS 1999", BY ZI ZHANG, M.B., M.P.H. AND BRUCE COHEN, PH.D., DIVISION OF HEALTH STATISTICS RESEARCH AND EPIDEMIOLOGY, BUREAU OF HEALTH STATISTICS, RESEARCH AND EVALUATION AND BARBARA FERRER, PH.D., DEPUTY DIRECTOR, BOSTON PUBLIC HEALTH COMMISSION:

Mr. Zi Zhang, M.B., M.P.H., said in part, "…Compared to the United States, Massachusetts is doing quite well on virtually all perinatal indicators. The Massachusetts teen birth rate was substantially lower than the U.S. rate. Early access to prenatal care as measured by women receiving prenatal care in their first trimester is higher in Massachusetts. The low birth weight rate was lower and, overall infant mortality rate was twenty-eight percent below the U.S. average…There has been consistent improvement over the last nine years in most Massachusetts perinatal indicators. Teen birth rate was down by twenty-five percent and the overall infant mortality rate has declined about twenty-six percent. Most importantly, the infant mortality rates are declining for all race, ethnicity groups. However, black non-Hispanic infant mortality has not been declining as much as the white non-Hispanic infant mortality or the Hispanic infant mortality. Disparity between the non-Hispanic white and non-Hispanic black infant mortality rates has not been improved over the last decade. One indicator not declining is low birth weight. It has risen about twenty-two percent…One factor contributing to the increasing number of low birth weight infants is the changing age distribution of women giving birth in Massachusetts. The number of women over the age of thirty giving birth is rising dramatically. This has an impact on low birth weight rates since older women tend to have a higher percent of low birth weight infants. In addition to a natural rising low birth weight as women age, we continue to see the trend of increasing multiple births. In fact, the number of multiple births has risen forty-one percent from 1990 to 1999. This increase in multiple births effects the low birth weight rate, too. Another trend emerging is that there is an increase in Cesarean deliveries in Massachusetts, as well as the United States, since 1997. C-section delivery was the method of delivery for 22.4 percent of all Massachusetts mothers in 1999."

Mr. Zhang continued, "We also monitor how many women reduced the amount of cigarettes they smoked during their pregnancy. Of the fifteen thousand women who reported smoking before they were pregnant, about two thirds of them either quit or reduced the amount of cigarettes they smoked. The percentage of women who reported smoking during pregnancy has improved significantly over the past decade. In 1990, one out of five reported smoking during pregnancy. In 1999, it is one out of ten. There has been a steady decline in the maternal smoking rate since the Department began its tobacco control program in 1993. We also examine birth characteristics by education. Women with less education are more likely to have low birth weight infants, are more likely to smoke during pregnancy, and they are more likely to receive public financed prenatal care. On the other hand, women with a better education are more likely to have

Cesarean deliveries, more likely to have multiples, more likely to breastfeed, and more likely to have low birth weight infants. It is encouraging to note that among the thirty largest communities in Massachusetts, none had an average infant mortality rate greater than ten deaths per one thousand at birth over the last three years. We hope that this is an indication that things are going in the right direction. Among the thirty largest communities in Massachusetts, Lawrence, Lowell, Springfield, Pittsfield, and Worcester had the lowest rate of timely access and the use of prenatal care, based on timing and the number of prenatal visits, not a qualitative judgement of contents of the care…"

Mr. Zhang said in summary, "First, perinatal indicators in Massachusetts are good. The infant mortality rate is the second lowest in Massachusetts history. The teen birth rate is stable and is one of the lowest since 1990, and four out of five women received timely prenatal care. However we do need to closely keep track of the black infant mortality rate and trend in low birth weight rate. Second, compared to the United States, Massachusetts 1999 perinatal indicators look good. The Massachusetts infant mortality rate was lower. Low birth weight rate was seven percent lower and the teen birth rate was forty-six percent lower. Third, we continue to see the unique Massachusetts pattern emerging in the past decade; more births to highly educated women over the age thirty, more multiple births, and a higher percentage of low birth weight infants. Fourth, disparity by ethnicity, by education, and among communities persists in Massachusetts. For example, infant mortality rates for blacks is substantially higher than for whites, and less educated women are much more likely to smoke cigarettes while they are pregnant and much more likely to receive inadequate prenatal care. Finally, we need to recognize the importance of birth data. It is one of the key surveillance data sets in our Department, and it is important for research and program development. It is extremely important that all physicians, other medical professionals, and the hospital administrators sustain the effort to provide timely data of the highest quality."

Next, Mr. John Auerbach, Director, Boston Public Health Commission, said in part, "In terms of initially looking at the births in Boston, we have had, in 1999, a continuation of a trend that has existed since 1996, or a slight increase in terms of birth overall, increasing about four percent since 1996, or about three hundred births. The racial composition of the mothers who have given birth in 1999 is roughly the same as it has been in previous years, which is slightly more than a third of the births to white women, slightly less than a third to black women, and about seven percent to Asian-American women. The age of women who gave birth in Boston has remained relatively the same from 1999 when compared to 1998 with some slight decreases in the under twenty age range…We have seen decreases in births to adolescents, ages fifteen to nineteen. They accounted for 9.5 percent of the approximately eight thousand births in 1999 compared to 10.4 percent in 1998, and this is the third year in a row that the percentage of births to adolescents was below eleven percent. This is similar to a national trend, but it has been very significant in Boston where we have seen from 1991 to 1999, a decline of twenty-nine percent in terms of adolescent birth rates. Also, a wonderful and promising indicator is the information regarding women who smoke during pregnancy. Smoking during pregnancy declined across all age groups with the exception of the women who are between twenty and twenty-four where an increase has occurred. Among adolescents,

those under age twenty, smoking during pregnancy declined by thirteen percent from 19.5 percent in 1998 to 8.3 percent in 1999, and women ages twenty-five to twenty-nine experienced the largest, a remarkable decline of forty percent of smoking during pregnancy form 9.2 percent in 1998 to 5.5 percent in 1999. The percentage of pregnant Boston women who smoked during pregnancy really has continued to decline for all races, with the exception of Asian-American women. Between 1991 and 1999, white women, who had the highest percentage of self-reported smoking during pregnancy, experienced a remarkable sixty-three percent decline in smoking. Black women who had the second highest percentage, had a decline during those same years. However, we are concerned about the percent of Asian women who smoke while pregnant, which has increased in 1999 over 1998. That is a trend that we will pay particular attention to. The other area where we are seeing the increases in adequacy of prenatal care occurred for women in all age groups with the greatest improvement experienced by women under twenty and women over thirty-five years of age. With regard to adequacy of prenatal care considered by race, we have seen the percentages of mothers of all racial and ethnic groups receive adequate prenatal care continue to increase, as well, in 1999; and importantly, the biggest increases were among women of color. Between 1998 and 1999, the receipt of adequate prenatal care improved by five percent for black women, six percent for Hispanic women, six percent for Asian women."

Dr. Barbara Ferrer, PhD., Deputy Director, Boston Public Health Commission, said in part, "We had fifty-nine infant deaths in Boston this year in 1999. That is nine more deaths than we had in 1998, and it also led to an increase in the rate of deaths for infants, which is up to 7.4. The increase in infant mortality is directly related to an increase in the neonatal infant mortality, that is in the first thirty days after birth. We have a consistent reduction in post-neonatal mortality rates in Boston. That is the good news. We are down to the lowest we have been since 1991 in terms of post-neonatal mortality. Infant mortality rates by race and ethnicity also sheds light on an increasing challenge for us in Boston. The disparity between black and white deaths for babies in Boston continues to trouble us. Black babies died at about two and a half times the rate of white babies in 1999. The rate for black infant deaths was 13.1 and, for white infant deaths, it is 5.6; and, for Hispanics, it was 4.1. We had sixteen white babies die. We had thirty-four black babies die. That is about sixty percent of our deaths in Boston. There were seven Hispanic infant deaths, one Asian death, and two of unknown race and ethnicity. Nonetheless, the black rate is still significantly higher than all the other rates. Black infants were about two and one half times more likely to die in the first two years. 1998 and 1999 have shown a troubling trend in an increase in the disparity between black and white infant deaths in Boston. In 1999 in Boston, we had done a few new things and I think they are worth noting. One is, we partnered with the state to implement First Link citywide in Boston. This is a program that allows us to offer to all new parents a home visit after they leave the hospital. That is a universal home visiting program that we have in Boston and we do it with both support and financial resources that we are getting from the state. We also introduced a new van, a public van that we call the Health Connection van. It goes throughout the city and offers a lot of public health education and efforts at making sure that folks are well linked to health services. We expanded our adolescent services in Boston in 1999 significantly. We added additional resources that would allow

us to expand our adolescent wellness program and also increase the staffing and the resources at seven school-based health centers that the city is running in the public high schools in Boston. Home visiting and case management services in Boston served about fourteen hundred women in 1999, as well…We are also going to start supporting the development of a computerized application process that will improve access to federal, state and local programs. We are going to continue to hold onto the strategy of improving women's health and making sure that our efforts continue to target the necessity to focus on womens health issues."

"INFORMATIONAL BRIEFING ON MODEL REGULATION FOR BODY ART ESTABLISHMENTS":

Ms. Nancy Ridley, Assistant Commissioner, Bureau of Health Quality Management, said in part, "…We have developed a set of restrictions that, if you are under the age of eighteen, we are recommending no tattooing, that there shall be no branding or scarification; and, as far as piercing is concerned, piercing will be okay if you have parental consent and parental presence, except for the piercing of genitalia. There were a combination of reasons. The first and foremost of which is public health protection and safety, obviously in terms of compliance with a lot of the after care types of requirements. We felt it was something that was best left to the more mature individuals who might adhere to many of the after care standards that need to be taken care of once you have one of these invasive procedures done. The second reason is that the three types of procedures that were strongly advocating be prohibited for minors are ones that are permanent in nature. They are far more permanent in nature than some of the simpler piercings would be. The tattoing can be, under certain circumstances, at least partially removed, but at great expense and often times leaving residual scarring behind. Branding and scarification is a permanent procedure that results in scarring and it would require some fairly extensive plastic surgery to reverse.

The other changes that we have made in these model regulations include getting a little more specific in terms of tattooists and piercers and the types of training and experience you really want them to have. We learned an awful lot ourselves about this industry when we were meeting with an ad hoc advisory committee, as well as throughout the hearings, and it appears quite clear that you want everyone to have a certain core set of trainings that would include training in infectious disease processes and pathogen control, sort of the universal precautions type of approach to preventing disease from an infectious organism standpoint. Beyond that, we have included courses in CPR, as well as a basic first aid course. Then, when it gets beyond those core types of trainings, we found that both tattooists and piercers felt that one size does not fit all in terms of what specific training they need. For body piercers, it would be some type of course work in anatomy and physiology due to the numbers and nature of the body parts being pierced and, for tattoists, it would be a course in skin care, probably similar to what the aestheticians type training is for cosmetology. So if you are going to go in the piercing direction, course work, training in anatomy and physiology. If you are going to go in the tattoo direction, it would be on skin care and the dermatologic types of conditions…There is a disclosure statement that talks about some of the respective health

risks for the different procedures as well as clearly expressing the fact that, in one case, the tattooing, there is an absolute prohibition about blood donations for a year afterwards; and in the case of piercings, there are some restrictions also. They can vary from state to state, but there are restrictions in the donation of blood products after piercing as well.

There is also a health history and informed consent section where we have got six or seven different conditions, such as diabetes, hemophilia, skin diseases, allergies to pigments and dies, epilepsy, use of medication that may inhibit clotting, and may cause problems with healing and other conditions which may put the client at risk in terms of having an invasive procedure either of a piercing or a tattooing. The model calls for the actual client to sign that they have been advised of these potential health risks and that they do not have a condition that prevents them from receiving body art. The after care instructions, again, differ slightly depending upon whether it is a piercing or a tattooing, and we have provided the model statements in this disclosure form. By having this all on one document, and having the client or the legal guardian of a minor, if it is one of the permitted procedures for minors, sign that sheet, a copy gets kept with the body art establishment, as well as it is given to the client. Then it seems to be a fairly simple way for compliance and for making sure that the potential clients get all of the information that they need.

The structure is laid out for permits for both the facility as well as for the individual operators. There was one very controversial issue that came up, and it has to do with these piercing guns people see in the shops where ear lobes get pierced. We took in a lot of comment. The professional body piercers would like to see those guns outlawed, prohibited across the board, even for ear lobes. Apparently they are being used on other body parts which they are absolutely not intended for use on. We have limited those guns using pre-sterilized ear and clasp sets to use on the ear lobe, not allowing them to be used on the rest of the ear, or on any other body part. We have tried to restrict the use of the guns without prohibiting them outright for the lobe itself. We have tried to follow the legislation to the maximum extent possible that is pending up on the Hill in drafting these regulations. ...We are recommending to the legislature that perhaps they adopt these restrictions into the proposed statutory legislation as well."

NO VOTE – INFORMATIONAL ONLY

PROPOSED REGULATIONS:

INFORMATIONAL BRIEFING ON PROPOSED REGULATIONS ON CONFIDENTIAL BIRTH INFORMATION – 105 CMR 305.000:

Attorney James Ballin, Deputy General Counsel, said, "These are new regulations that the Department is promulgating to comply with amendments to Mass General Laws Chapter 111, Section 24B and the amendments require the Department of Public Health to issue regulations regarding the disclosure of confidential birth information before releasing such information to researchers. Since the Department has had a formal process for reviewing and approving requests by researchers for birth records for many years

now, what we have drafted is essentially regulations which are very similar to our current policy…During the last five to ten years, the Department has developed a comprehensive review process to evaluate requests by researchers for access to confidential birth information to conduct their research. This review process is intended to insure that the study has a legitimate public health purpose and that there are measures to protect the confidentiality of the information to the greatest extent possible.

Under this established review process, a researcher requesting access to confidential birth information must complete a detailed application describing the public health purpose of the study, the study design, specific birth information that is required for this study, as well as security and confidentiality measures that the researcher will take to protect the information. A Department review committee consisting of senior department staff meets monthly to review these applications and the review committee determines whether or not they meet the minimum criteria that have been established by the Commissioner for requests for this information. The Committee then either makes a recommendation to the Commissioner or, in some cases, requests revisions or clarifications from the researcher. The Chair of the Department's Institutional Review Board (IRB), as well as the Legal Office and Policy Office also participate in this process. Researchers who receive approval from the Commissioner for access to confidential birth information are also authorized under Chapter 111, Section 24A, which essentially protects the confidentiality of information used for research and states that the information shall not be admissible as evidence in any legal proceeding. These proposed regulations are being promulgated in order to comply with this new statutory requirement under Section 24B, but what they essentially do is formalize the Department policy. The regulations specify who has to report the required birth information and the manner in which it is required to be reported. It states that birth information is considered confidential and that it is exempt from public records law. Then the next three sections discuss who may have access to the confidential birth information depending on the degree to which that information may identify an individual. The next section of the proposed regulation describes the application review process. Finally, the regulations state the specific restrictions and limitations that the Department imposes on any researcher as conditions for temporary use of the confidential data for their research purposes…Just to list a few of these, some of these include limitations on release or re-disclosure to any non-authorized person; prohibitions on use of the data for any unproved purpose; a clarification that the data is provided for temporary use only and that the Department maintains ownership and control of the data at all times.

There are restrictions on identifying an individual in public or released reports, requirements to submit annual renewals for continued use of the data, and the execution of a written agreement by the principal investigator insuring that compliance with the restrictions and limitations are met. Finally, the Department will be convening an advisory committee to the Registry of Vital Records and Statistics and they will be providing comments on the proposed regulations. The Department will be conducting a

public hearing on the proposed regulations in early March and hopefully will be back before you during the March meeting to request your final approval in promulgating these regulations."

NO VOTE – INFORMATIONAL ONLY

INFORMATIONAL BRIEFING ON PROPOSED REGULATIONS REGARDING MINIMUM STANDARDS FOR BATHING BEACHES – STATE SANITARY CODE CHAPTER VII – 105 CMR 445.000:

Mr. Howard Wensley, Director, Division of Community Sanitation, said in part, "…The proposed regulations will require…that the bathing water be tested on a weekly basis during the bathing season instead of the current regulatory requirement of two weeks…We are amending the requirement as far as posting the beach when the bacteria levels are exceeding. The current regulation basically requires that they be posted every hundred linear feet of the beach. The proposed regulations require posting at all entrances and in all parking lots. We will also set up specific standards and protocol for sample collection and sample analysis. The regulations will require that Boards of Health will be responsible for their implementation and that the Department of Public Health will take on the responsibility for monitoring and enforcing these regulations for state operated beaches. We are doing this at the request of both the local Boards of Health and the state agencies that operate beaches. The statute also requires that Boards of Health report to the Department the results of the testing. We have set up a mechanism through the regulations where all elevated levels or findings of contamination will be reported to the local Board of Health and the Department within twenty-four hours of noting that, and all routine levels will be reported to the Department by October 31st of each year.

The legislation requires that the Department provide an annual report of the condition of the beaches within the Commonwealth, and this reporting by the Boards of Health, will provide us with the information to be able to do that. We have also built into the regulations a variance procedure because it is very clear to us that there may be some beaches out there where weekly testing is not warranted, where there have not been any problems. We have also developed a variance procedure whereby, if after two years of experience using the indicator organism that will be required, and that a sanitary survey will be taken, which basically is a survey of the area indicating that there are no potential pollution sources, the local Board of Health, with concurrence of the Department, will be able to grant a variance frorm the weekly testing. However, the provision is in there that at least annual testing will be required of those beaches and, each location will have to be taken on an individual basis.

One of the other provisions of the statute, however, was that the local Mandate's Office, or the State Auditor's Office was required to do a cost benefit analysis and a determination as to whether or not the particular statute had an impact on the prohibition of any state law or regulation putting new mandates on local municipalities. However, even though the statute required this finding of this study, it did not say that if a local mandate finds that it is a problem, the statute is no longer valid…One of the other issues

in the statute is that there is a provision that the Department of Public Health administer grants to local Boards of Health upon appropriation up to fifty percent of the costs of carrying out this program. The rock and the hard place we are between is that their local mandate states that it is a new mandate and, up to this particular date, no additional funding has been forthcoming from the legislature. The Department, however, does intend to move forward with the public hearing process and with these regulations with the hope that those additional resources will be available before these regulations are in place; and, if they are not, we obviously will be subject to challenge from the local municipalities saying, we don't have to do this because the funding is not there. The hearings will be in early March, and we anticipate we will be back before the Council with final regulations at the March meeting."

Attorney Donna Levin, General Counsel, Department of Public Health noted that if there is no forthcoming legislative appropriation, staff will have to consider whether the Department should promulgate these or not. Discussion continued and it was noted about $300,000 is needed by the Department to carry out the mandate.

NO VOTE – INFORMATION ONLY

REGULATIONS:

REQUEST FOR PROMULGATION OF REVISIONS TO THE REGULATIONS FOR LEAD POISONING PREVENTION AND CONTROL – 105 CMR 460.000:

Mr. Paul Hunter, Director, Childhood Lead Poisoning Prevention, said, "We are here to ask for final approval for amendments to the Childhood Lead Poisoning Prevention regulations. The most significant change regards the previously mandatory four year old screening of all children in Massachusetts. Again, after significant deliberation of the Statewide Screening Committee, the Governor's Advisory Committee and a review of significant amounts of our data, it was determined that we could change that requirement and target the fourth year screening to children in high risk communities; and, on an annual basis we will decide which communities throughout the Commonwealth constitute high risk for lead poisoning among their childhood population. There are a number of other changes in addition. One would require that the medical community provide standard medical follow up in case management services to children identified with elevated blood lead levels. Another will require the electronic reporting of all lead poisoning screenings for children unless a waiver is issued by the Department and the program."

Mr. Roy Petre, Assistant Director, Childhood Lead Poisoning Prevention, said in part, "The first set of mandatory screening regulations were promulgated by the Department in 1991 and there has been no change until now. We sent out letters and copies of proposed regulations to over forty-five hundred pediatricians, every pediatrician registered in medicine in Massachusetts. The most remarkable thing is, we received only one comment from a pediatrician, which I think says a lot about the acceptance of these

regulations in the medical community and that comment suggested that there be a change in the interval between the first and second year screening. This particular provider did not realize that, in these regulations, there is complete flexibility and discretion given to providers to screen anytime they deem it to be medically warranted. So, of course, we did not make that change. One Board of Health, in regard to the fourth year targeting screen, suggested that a child who lives in a high risk community could move out of that community to one that was not high risk and, thereby, miss an opportunity to be screened. In putting together these regulations, however, we did extensive research on our really enormous screening database to determine just what the fourth year targeted screen would have in terms of its effects unidentifying children as lead poisoned at that year, and what we found is that, under these regulations with the target screening, combined with the mandate for provider follow-up for children with blood lead elevations, that over ninety-five percent of children who are lead poisoned would be identified and what we have also seen is a decline in the number of children over the years identified at that later age. We have also seen a decline right now in the screening of children in the high risk communities and we are hopeful that, by drawing attention to this fourth year screen through targeting, that we will actually see an increase there. So we are comfortable in maintaining the targeted screening provision. One other aspect to these regulations that is significant is the focus on laboratory reporting of all analysis. This is an area where we have been paying particular attention to make sure that poisoned children are promptly reported…Four labs responded to our proposed regulations requiring that all laboratories report all results electronically to us. These four labs made the point that this would put them at a financial competitive disadvantage. So we are maintaining that regulation that all screening results be reported in a secure electronic format, but we have a waiver provision for labs who submit very low volume results…"

After consideration, upon motion made and duly seconded, it was voted unanimously (Council Members Askinazi and Cudmore not present to vote) to approve the **Request for Promulgation of Revisions to the Regulations for Lead Poisoning Prevention and Control – 105 CMR 460.000;** that a copy of the approved regulations be attached to and made a part of this record as **Exhibit Number 14,693**; and a public hearing was held on September 11, 2000.

REQUEST FOR PROMULGATION OF FINAL AMENDMENTS TO EMERGENCY MEDICAL SERVICES SYSTEM – 105 CMR 170.000:

Ms. Tracy Miller, Deputy General Counsel, said in part, "…We are here today to request that the Public Health Council approve for final promulgation the amendments to 105 CMR 170.000 which is the Emergency Medical Services System Regulations…This is a set of regulations that focuses primarily on the role of the regions and their duties and responsibilities in coordination with the Department for the implementation of the new statute EMS 2000. We held two public hearings with regard to these regulations…The bulk of the comments actually related to the five EMS regions and their roles and responsibilities. Previously 111C, the statute that regulates the EMS system, only referred to the regions in the most general way to ask for regional coordination, and only with the passage of EMS 2000 last March did the statute actually lay out the structure of

the EMS councils, their roles, their responsibilities and how those councils were to work with the Department as the lead agency, and how the regions would work in the implementation of the new EMS system. We took this statutory framework and tried to set forth that statutory framework with more details in the regulations and this is the area where we got the most comments from the individual regions…Several regions commented that the Department should remove the provision that required regional EMS councils to comply with the State Ethics Laws and move that to the contracts. We decided to leave the general framework in the regulation but simplify it. There was some concern that the language was confusing. So we simplified the language and we indicated that there was a requirement that they needed to comply with the ethics provisions, the conflict of interest provisions and that the specific details would be laid out in the contracts. The area that garnered the most comments, was with regard to a new requirement that the Department placed in the regulation that the funds that were given to the individual EMS councils could not be used by the council for direct training of EMS personnel. This is an area that the Department has worked with the councils for the last several years in trying to work out a system that we believe works and there was a great deal of comment in this area. Several of the regions rely to a great extent on the training programs for additional funds. The Department was aware of that issue and worked with them…In response to these comments, the Department clarified the language and put in place some flexibility to work with the regions and the regional contracts and the final regulation now phases in this prohibition beginning with Fiscal Year 2002, and what the regulation now does is it says, except as provided in the regional contract, that the regions will not use Department funds. It does not mean they cannot use other funds, but they will not use Department funds to conduct direct training of EMS personnel if it conflicts with the regulatory duties and if those training programs are provided by any other educational provider in the marketplace."

Attorney Miller continued, "The last three areas where we received substantive comments are areas that the Department determined not to make changes in the regulations. The first is, there is a requirement that Advanced Life Support Services will meet a twenty-four hour, seven day a week operating standard either within three years of licensure of the ALS level, or three years from the date of implementation of these regulations. This is an area where we received comments in both directions. We received comments from many rural providers with concerns that they will not be able to meet the standard, and we received comments from urban providers, where they believe that we should not have a three year phase-in period, that this standard should be implemented right away. The Department determined to leave the regulation as it stands, and believes that the three year phase-in is important. What is important, also to note, is that this is a national standard; and, it is a standard that is already met by providers in Massachusetts; and, if there are pockets of areas that cannot meet the standards, we do have waiver provisions in our regulations. We can look at those providers but the Department believes this is a standard that should be met and will be implemented in the next three years.

The second area of substantive comments includes a requirement that EMT's that are certified in other states that are attempting to be certified in Massachusetts will have to

take a Massachusetts written exam. The Department has the discretion to waive the practical portion of the exam, but will require a Massachusetts exam. We received substantive comments in this area, particularly by services that are concerned that this may cause a delay in hiring, particularly paramedics, which from time to time are in short supply. The Department decided not to make a change in this area. There is a provision in our regulations that would permit a temporary waiver, to allow an EMT to work while they are going through the testing process. That addresses the hiring concerns and it is the Department's belief that Massachusetts does have its own EMT exam. It tests particularly Massachusetts protocols and we believe that it is an important test for all certified EMT's to go through."

Attorney Miller concluded, "Finally, the last area where there was substantive comment relates to a fee increase. The Department proposed a renewal fee increase, a biannual increase to seventy-five dollars. This would be an across the board increase for all EMT's. The Basic Life Support level is now twenty-five dollars. The Advanced Life Support is now thirty-five dollars. The Department has not sought an increase for EMT certification since 1987. Since that time, there have been substantial increases in costs. It is also the intent to provide increased services for this increasing fee. So the Department declined to make a change in that area as well. That is a summary of the changes that were made and not made…"

After consideration, upon motion made and duly seconded, it was voted unanimously to approve the Request for **Promulgation of Final Amendments to Emergency Medical Services System – 105 CMR 170.000**: that a copy of the approved regulations be forwarded to the Secretary of the Commonwealth; and that a copy of the amended regulations be attached to and made a part of this record as **Exhibit Number 14,694**. The Department held two public hearings: Tuesday, October 24, 2000, in Springfield, and Monday, October 30, 2000, in Dedham.

REQUEST FOR FINAL PROMULGATION OF AMENDMENTS TO HOSPITAL LICENSURE REGULATIONS GOVERNING SATELLITE EMERGENCY FACILITIES (SEFS) – 105 CMR 130.000:

Attorney Carl Rosenfield presented the Request for Promulgation of Amendments to Hospital Licensure Regulations Governing Satellite Emergency Facilities – 105 CMR 130.000. He said in part, "We are here today to request approval for final promulgation of the proposed amendments to hospital licensure regulations governing satellite emergency facilities. Satellite emergency facilities are those facilities located off the main campus of the hospital which are under the license of the hospital; and under the terms and conditions provided in these regulations, would be able to receive patients through unscheduled ambulance transport. In addition to establishing substantive requirements for the satellite emergency facilities, the regulations also lay out a process that guarantees community involvement in hospital planning and decision to establish an SEF. We had a public hearing on September 18th at which two people testified in support of the regulations. In addition, we had one written comment on the periodicity of reporting and the suggestion was made that, after the first two years of quarterly

reporting, we move to reporting on an annual basis and we thought that was a reasonable request, so we have made the modification. In addition, there are two technical changes that need to be made as a result of an oversight. In Section 130.825, the title should be changed from Public Hearing to Public Meeting because all the other references are to a public meeting and that is part of the community process. And, in Section 130.829, there is a word left out on the first line. After SEF should be 'must.' We would like to request that the Council approve these regulations for final promulgation."

After consideration, upon motion made and duly seconded, it was voted: Chairman Koh, Mr. Sherman, Dr. Askinazi, Ms. Slemenda, Ms. Masaschi, Mr. George, Jr. in favor; Dr. Sterne opposed to approve with corrections, the Request for **Final Promulgation of Amendments to Hospital Licensure Regulations Governing Satellite Emergency Facilities (SEFs) – 105 CMR 130.000**; that a copy of the approved regulations be forwarded to the Secretary of the Commonwealth; and that a copy of the amended regulations be attached to and made a part of this record as **Exhibit Number 14,695**. A public hearing was held on September 18, 2000.

REQUEST FOR RENEWAL OF EMERGENCY PROMULGATION OF AMENDMENTS TO HOSPITAL LICENSURE REGULATIONS REGARDING NEEDLESTICK INJURY PREVENTION – 105 CMR 130.000:

Attorney Carl Rosenfield, Deputy General Counsel, said in part, "At its meeting on October 24, 2000, the Public Health Council adopted emergency regulations implementing Chapter 252 of the Acts of 2000, An Act Relative to Needlestick Injury Prevention. The regulations were specifically required by Chapter 252, which became effective on November 15, 2000. Pursuant to Massachusetts General Laws Chapter 30A, the emergency regulations remain in effect for a period of ninety (90) days. During that period the public hearing process must be completed and the regulations finalized. For these amendments the emergency period expires on February 22, 2001. Because of scheduling difficulties a public hearing on the emergency regulations could not be held until January 24, 2001. The delay in holding the hearing made it impossible for the Staff to return to the Council for final adoption before the February 22, 2001 expiration of the emergency period. Accordingly, Staff is requesting the Council to adopt these regulations as emergency regulations again. This action will insure that the regulations remain in effect without interruption until the public hearing process is complete. Staff anticipates returning to the Council for final adoption of the regulations in February. So we are requesting a re-adoption as emergency regulations to allow the completion of the process and to allow the regulations to remain effective without interruption."

After consideration, upon motion made and duly seconded, it was voted: unanimously to approve the request for **Renewal of Emergency Promulgation of Amendments to Hospital Licensure Regulations Regarding Needlestick Injury Prevention – 105 CMR 130.000**; that a copy of the emergency regulations be attached to and made a part of this record as **Exhibit Number 14,696**; and that a copy of the emergency regulations be forwarded to the Secretary of the Commonwealth.

DETERMINATION OF NEED PROGRAM:

COMPLIANCE MEMORANDUM:

PREVIOUSLY APPROVED DON PROJECT NO. 2-3956 OF HEALTH ALLIANCE HOSPITALS – PROGRESS REPORT ON COMPLIANCE WITH CONDITIONS OF APPROVAL FOR TRANSFER OF OWNERSHIP:

Mr. Jere Page, Senior Analyst, Determination of Need Program, said, "This is the fourth time we have been here in front of the Council with regard to a progress report on this particular project. The last time was last May. At that point, we found that Health Alliance was in substantial compliance with the eleven conditions that were conditions of approval of the transfer of ownership in 1998. We are still finding them in substantial compliance with the eleven conditions that were conditions of approval of the transfer of ownership in 1998. We are here basically because there was some contention about the provision of emergency services at the Burbank campus. You may recall last May we told you that the Health Alliance people were going to close down full emergency services at Burbank Campus and make that an urgent care center. That happened on September 1st and we have written a report to the Legislature regarding that whole issue. Basically, they are in compliance and that is why we are here again today."

After consideration, upon motion made and duly seconded, it was voted unanimously to approve staff's recommendation to return in six months with a progress report on compliance of the conditions of approval for Transfer of Ownership on **Previously Approved DoN Project Number 2-3956 of Health Alliance Hospital.**

CATEGORY 1 APPLICATION:

PROJECT APPLICATION NO. 4-3983 OF THE CHILDREN'S HOSPITAL – SUBSTANTIAL CAPITAL EXPENDITURE TO REPLACE MICU AND CICU BEDS:

Mr. Jere Page, Senior Analyst, Determination of Need Program, said, "This is Children's Hospital's application. Their request seeks approval to replace the existing 18-bed, multi-disciplinary intensive care unit, and their existing 22-bed cardiac intensive care unit with two 24-bed intensive care units on the hospital's campus. This would be part of a brand new eleven-story building. These two units would take up the seventh and eighth floors. The rest would be administrative and ambulatory care functions, which are not subject to DoN review. We found that the project meets all nine review factors of the DoN regulations. The maximum capital expenditure in this is just over twenty-two million dollars. They have agreed to put up over five hundred thousand dollars in

community initiative money over five years in two separate programs. One is regarding health and well being of children, adolescents and families in the City of Boston. That is thirty thousand dollars a year for five years a total of a hundred and fifty thousand dollars. The other is seventy thousand dollars per year over five years for a total of three hundred and fifty thousand dollars. It is a substantial amount of money from what we have normally seen with regard to these DoN projects. We are recommending approval of this project…"

After consideration, upon motion made and duly seconded, it was voted unanimously (Council Member Sherman recused himself from the discussion and vote; not due to 268A) to approve **Project Application No. 4-3983 of the Children's Hospital** for Substantial Capital Expenditure to Replace MICU and CICU Beds, (a summary is attached and made a part of this record as **Exhibit Number 14,697**), based on staff findings, with a maximum capital expenditure of $22,279,000 (July 2000 dollars) and first year incremental operating costs of $2,040,000 (July 2000 dollars). As approved, the application provides for new construction and renovation to replace both the existing 18-bed Multidisciplinary Intensive Care Unit (MICU) and 22-bed Cardiac Intensive Care Unit (CICU) with two 24-bed intensive care units on the Children's Hospital campus. This Determination is subject to the following conditions:

1) The Applicant shall accept the maximum capital expenditure of $22,279,000 (July 2000 dollars) as the final cost figure except for those increases allowed pursuant to 105 CMR 100.751 and 752.

2) The Applicant shall contribute 20% in equity ($4,455,800 in July 2000 dollars) to the final approved MCE.

3) The total gross square feet (GSF) for this project shall be 50,280: 45,120 GSF for new construction to replace the existing MICU and CICU, and 5,160 GSF for renovation of existing hospital space to attach the new clinical building to the Hospital's Main Building.

4) The Applicant shall provide a total of $500,000 (July 2000 dollars) over 5 years to fund the following community health services initiatives:

    1. $30,000 per year over five years for a total of $150,000 to fund mini-grants to the neighborhoods of the Alliance Coalition for the City of Boston. The mini-grants shall be established to deliver prevention programs to improve the health and well being of children, adolescents and families as directed by the Alliance operation team, which will include a designated member of Children's Hospital. The prevention programs shall be consistent with the priorities of Children's Hospital, including asthma, injury prevention and access to health services.

    2. $70,000 per year over five years for a total of $350,000 to fund dental health services at the Martha Eliot Community Health Center or at any other community health center site.

3. After two years of funding these programs, Children's Hospital, with the Department's consent, may identify alternative recipients of any of the proposed funds.

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The meeting adjourned at 12:15 p.m.

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Howard K. Koh, M.D., Chairman
Public Health Council

LMH/SB